Complete Summary

GUIDELINE TITLE

pH testing. Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing.

BIBLIOGRAPHIC SOURCE(S)

Nichols JH, Taylor D, Varnholt H, Williams L. pH testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 120-5. [58 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Any disease or condition requiring pH testing including:

- Achlorhydria
- Gastroesophageal reflux disease
- Placement of gastrointestinal (GI) feeding tubes
- Chemical burns

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Evaluation

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Clinical Laboratory Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To examine the application of evidence-based medicine (EBM) to the form of diagnostic testing known as point-of-care testing (POCT)

  Note: For the purpose of this document, POCT is defined as "clinical laboratory testing conducted close to the site of patient care, typically by clinical personnel whose primary training is not in the clinical laboratory sciences or by patients (self-testing). POCT refers to any testing performed outside of the traditional, core or central laboratory."

- To systematically review and synthesize the available evidence on the effectiveness of POCT, with specific focus on outcomes in the areas of:
  1. Patient/health
  2. Operational/management
  3. Economic benefit
- To address the use of pH paper in determining gastric pH, placement of gastrointestinal (GI) feeding tubes, and treatment of chemical burns

TARGET POPULATION

Patients requiring pH testing, including:

- Patients with chemical burns in emergency department and urgent care
- Patients with achlorhydria and gastric reflux disease
- Patients undergoing the placement of nasogastric tubes

INTERVENTIONS AND PRACTICES CONSIDERED

1. Continuous pH monitoring for the diagnosis of gastroesophageal reflux (GER) disease
2. pH testing to confirm the placement of feeding tubes

Note: The following applications of pH testing were considered but not recommended: intermittent testing by pH meter or litmus paper for GER and pH testing for diagnosis and treatment monitoring of chemical exposure.

MAJOR OUTCOMES CONSIDERED

- Patient outcomes such as severity of symptoms, length of stay in the emergency department, improved placement of nasogastric tubes
- Accuracy and utility of pH testing

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For a specific clinical use, pertinent clinical questions were formulated and key search terms were ascertained for the literature search. Searches were conducted on MEDLINE, OVID, and were supplemented with the use of the National Guideline Clearinghouse, the Cochrane Group, or evidence-based medicine (EBM) reviews. Additionally, authors' personal article collections were used. Acceptable citations were limited to peer-reviewed articles with abstracts, those published in English, and those involving human subjects.

To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Abstracts identified by the literature searches were reviewed by 2 individuals to determine initial eligibility or ineligibility for full-text review, using Form 1 (Appendix A - see the "Availability of Companion Documents" field). If there was not consensus, then a third individual reviewed the abstract(s). To be included in the full systematic review of the clinical question, articles selected for full text review were examined for at least 1 relevant outcomes measurement. The systematic review consisted of creating evidence tables using Form 2 (Appendix A - see the "Availability of Companion Documents" field) that incorporated the following characteristics:

1. Study design—Prospective or retrospective, randomized, and controlled, patient inclusion/exclusion criteria, blinding, number of subjects, etc.
2. Appropriateness of controls
3. Potential for bias (consecutive or nonconsecutive enrollment)
4. Depth of method description—full-length report or technical brief
5. Clinical application—screening, diagnosis, management
6. Specific key outcomes and how they were measured
7. Conclusions are logically supported

For the assessment of study quality, the general approach to grading evidence developed by the US Preventive Services Task Force was applied (see the "Rating Scheme for the Strength of the Evidence" field). Once that was done, an assessment of study quality was performed, looking at the individual and aggregate data at 3 different levels using Forms 3 and 4 (Appendix A - see the "Availability of Companion Documents" field). At the first level, the individual study design was evaluated, as well as internal and external validity. Internal validity is the degree to which the study provides valid evidence for the populations and setting in which it was conducted. External validity is the extent to which the evidence is relevant and can be generalized to populations and conditions of other patient populations and point-of-care testing (POCT) settings.

The synthesis of the volume of literature constitutes the second level, Form 5 (Appendix A - see the "Availability of Companion Documents" field). Aggregate internal and external validity was evaluated, as well as the coherence/consistency of the body of data. How well does the evidence fit together in an understandable model of how POCT leads to improved clinical outcome? Ultimately, the weight of the evidence about the linkage of POCT to outcomes is determined by assessing

the degree to which the various bodies of evidence (linkages) "fit" together. To what degree is the testing in the same population and condition in the various linkages? Is the evidence that connects POCT to outcome direct or indirect? Evidence is direct when a single linkage exists but is indirect when multiple linkages are required to reach the same conclusion.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The field of point-of-care testing (POCT), diagnostic testing conducted close to the site of patient care, was divided into disease- and test-specific focus areas. Groups of expert physicians, laboratorians, and diagnostic manufacturers in each focus area were assembled to conduct systematic reviews of the scientific literature and prepare guidelines based on the strength of scientific evidence linking the use of POCT to patient outcome.

Final guidelines were made according to Agency for Healthcare Research and Quality (AHRQ) classification (see the Rating Scheme for the Strength of the Recommendations field). The guidelines are evidence based and require scientific evidence that the recipients of POCT experience better health outcomes than those who did not and that the benefits are large enough to outweigh the risks. Consensus documents are not research evidence and represent guidelines for clinical practice, and inclusion of consensus documents was based on the linkages to outcomes, the reputation of the peer organization, and the consensus process used to develop the document. Health outcomes, e.g., benefit/harm, are the most significant outcomes in weighing the evidence and drafting guidelines.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were presented in open forum at the American Association for Clinical Chemistry (AACC) Annual Meeting (Los Angeles, CA, USA) in July 2004. Portions of these guidelines were also presented at several meetings between 2003 and 2005. Participants at each meeting had the ability to discuss the merits of the guidelines and submit comments to the National Academy of Clinical Biochemistry (NACB) Web site for formal response by the NACB during the open comment period from January 2004 through October 2005.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the levels of evidence (I—III) and grades of the recommendation (A, B, C, I) are presented at the end of the "Major Recommendations" field.

Note from the National Academy of Clinical Biochemistry (NACB) and the National Guideline Clearinghouse (NGC)*: The Laboratory Medicine Practice Guidelines (LMPG) evidence-based practice for point-of-care testing sponsored by the NACB* have been divided into individual summaries covering disease- and test-specific areas. In addition to the current summary, the following are available:

- Chapter 1: Management
- Chapter 2: Transcutaneous Bilirubin Testing
- Chapter 3: Use of Cardiac Biomarkers for Acute Coronary Syndromes
- Chapter 4: Coagulation
- Chapter 5: Critical care
- Chapter 6: Diagnosis and Management of Diabetes Mellitus
- Chapter 7: Drugs and Ethanol
- Chapter 8: Infectious Disease
- Chapter 9: Occult Blood
- Chapter 10: Intraoperative Parathyroid Hormone
- Chapter 12: Renal Function Testing
- Chapter 13: Reproductive Testing

Does the use of pH paper to diagnose and monitor treatment of chemical exposure in the emergency department and urgent care patient populations improve length of stay and severity of burn compared to empirical treatment (no monitoring)? (Literature Search 76 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 151. The guideline developers note that pH paper may have utility in monitoring the treatment of chemical exposure in the emergency department and

urgent care patient populations, but there is insufficient evidence to make a strong recommendation for or against its routine use. pH testing poses no risk to the patient, and the minimal cost of testing has led to its common availability. However, a systematic examination should be conducted to determine whether pH testing has an incremental benefit during irrigation therapy after chemical exposure that outweighs the time and expense required to maintain test quality training and documentation.
Strength/consensus of recommendation: I
Level of evidence: III (clinical experience, descriptive studies, case reports and opinion)

Does continuous gastric pH monitoring, compared to random gastric pH determinations, improve patient symptoms and severity in the management of achlorhydria and gastric reflux in inpatient and endoscopy patients? (Literature Search 77 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 152. The guideline developers recommend against the intermittent use of pH paper on gastric aspirates in the diagnosis of gastric reflux disease in favor of continuous monitoring. The role of pH testing to manage acid suppression therapy is controversial. Although the use of pH testing is common on critical care units, there is a lack of evidence that pH monitoring to adjust drug dosage improves either morbidity or mortality in these patients.
Strength/consensus of recommendation: C
Level of evidence: II and III (well-designed case-controlled, or relation trials and opinion)

Does the use of pH paper for assisting the placement of nasogastric tubes, compared to clinical judgment (air, pressure), improve the placement of tubes for inpatient, endoscopy, home care, and nursing home patients? (Literature Search 78 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 153. The guideline developers recommend the use of pH testing to assist in the placement of nasogastric tubes. Radiography is considered the gold standard means of determining tube placement, but there is fair evidence that pH testing can predict the position of nasogastric tubes while reducing the number of radiographs and exposure of the patient to additional radiation. The choice of measuring pH with an intragastric electrode or testing tube aspirates with a pH meter or pH paper will depend on consideration of the clinical limitations of each method, and there is conflicting evidence about which method is better.
Strength/consensus of recommendation: B
Level of evidence: II and III (prospective comparative trials and expert opinion)

Is one brand of pH paper better than another brand in improving patient symptoms and time to treatment of chemical burns in emergency and urgent care patients, and in improving the accuracy of nasogastric tube placement in inpatient, endoscopy, home care, and nursing home patients? (Literature Search 79 - Refer to Appendix B - see the "Availability of Companion Documents" field)

Guideline 154. There is insufficient evidence to recommend one brand of pH paper over another brand of pH paper for use in the treatment of chemical burns

or placement of nasogastric tubes.
Strength/consensus of recommendation: I
Level of evidence: III (case reports and opinion)

Definitions:

Levels of Evidence

I. Evidence includes consistent results from well-designed, well-conducted studies in representative populations.
II. Evidence is sufficient to determine effects, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; generalizability to routine practice; or indirect nature of the evidence.
III. Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack of information.

Strength of Recommendations

A - The National Academy of Clinical Biochemistry (NACB) strongly recommends adoption; there is good evidence that it improves important health outcomes and concludes that benefits substantially outweigh harms.

B - The NACB recommends adoption; there is at least fair evidence that it improves important health outcomes and concludes that benefits outweigh harms.

C - The NACB recommends against adoption; there is evidence that it is ineffective or that harms outweigh benefits.

I - The NACB concludes that the evidence is insufficient to make recommendations; evidence that it is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- It is hoped that these guidelines will be useful for those implementing new testing, as well as those reviewing the basis of current practice. These

guidelines should help sort fact from conjecture when testing is applied to different patient populations and establish proven applications from off-label and alternative uses of point-of-care testing (POCT). These guidelines will also be useful in defining mechanisms for optimizing patient outcome and identify areas lacking in the current literature that are needed for future research.
- pH testing can reduce the need for reliance on radiographic confirmation in every tube placement, providing efficiency and cost savings in patient management.

POTENTIAL HARMS

Inaccuracies in pH results can lead to undertreatment with acid inhibitors, inappropriate feeding tube placement, and premature discontinuation of irrigation for chemical burns, all of which have the potential for serious and costly patient consequences.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The material in this monograph represents the opinions of the editors and does not represent the official position of the National Academy of Clinical Biochemistry or any of the cosponsoring organizations.
- Point-of-care testing (POCT) is an expanding delivery option because of increased pressure for faster results. However, POCT should not be used as a core laboratory replacement in all patient populations without consideration of the test limitations and evaluation of the effect of a faster result on patient care.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Nichols JH, Taylor D, Varnholt H, Williams L. pH testing. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 120-5. [58 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

National Academy of Clinical Biochemistry - Professional Association

SOURCE(S) OF FUNDING

National Academy of Clinical Biochemistry

GUIDELINE COMMITTEE

Guidelines Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Preface and introduction. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. i-xvi.
- Appendix A: NACB LMPG data abstraction forms. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 149-153.
- Appendix B: literature searches. In: Laboratory medicine practice guidelines: evidence-based practice for point-of-care testing. Washington (DC): National Academy of Clinical Biochemistry (NACB); 2006. p. 154-186.

Electronic copies: Available in Portable Document Format (PDF) from the National Academy of Clinical Biochemistry (NACB) Web site.

Print copies: National Academy of Clinical Biochemistry publications are available through American Association for Clinical Chemistry (AACC) Press. To make a purchase or request a catalog, contact AACC Customer Service at 202-857-0717 or custserv@aacc.org.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on August 13, 2007. The information was verified by the guideline developer on September 24, 2007.

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